



PATENT APPLICATION

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10/22/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

James CASTILLO

Application No.: 09/954,494

Examiner: Kim, Vickie

Filed: September 17, 2001

Group Art Unit: 1614

For: ALCOHOL BASED TOPICAL ANESTHETIC FORMULATION AND METHOD

Attorney Docket: 3863.015

DECLARATION UNDER 37 C.F.R. §1.132

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I, James Castillo, 15412 15th Street, Lutz Florida 33549, declare
and state the following:

In March of 1980, I graduated from the University of Florida with a
Bachelors Degree in Pharmacy.

I have been involved in research and development relating to
pharmacology, and particularly anesthetics, since 1986, and consider
myself an expert in this field.

I am familiar with the subject matter and prosecution history of
the above-identified application, including the Office Action dated
June 05, 2002.

I have been personally involved in the development of the presently claimed compounds and am personally aware of the following historical events.

I note the Examiner's position in the Office Action dated June 5, 2002, that Sipos and Castillo combined teach the method according to the present invention.

The following experimentation was conducted by me, or under my direct supervision.

PROCEDURE

I was prepared to conduct a comparative experimentation to demonstrate that neither the Sipos or Castillo references teach an anesthetic that can be evaporated.

At the beginning, the basic idea was to perform an evaporation test in the Sipos formulation, the Castillo formulation, and the formulation of the present invention, and compare the results of the three tests.

The first step of the present experiment was the preparation of the formula disclosed in the Sipos patent.

Formulas in the Sipos patent require a cyclic alcohol in a base with ethanol and water. The only cyclic alcohol that we were able to obtain was 2-methyl-cyclohexanol (2MC). This chemical is hydrophobic, and, therefore, requires an emulsion to be made with ethanol and/or water.

The undersigned, and a group of his experienced laboratory staff, attempted to reproduce the Formulation of the Sipos reference disclosed in examples 7 and 10.

In both cases, it was observed that the 2MC separated from the water phase, producing two immiscible phases. Thus, an homogeneous formulation could not be obtained.

After consulting with my laboratory staff, we took the decision of adding to the Sipos formulation surfactants (as polysorbate 80 and sodium laurel sulfate) in order to mix the two phases and produce a homogenous formulation. The addition of the surfactants only slightly delayed the separation of the phases, but after a couple of minutes, the phases were separate.

The undersigned and his experienced laboratory staff used all their knowledge trying to mix the two phases without any success.

The next step was trying to obtain the product directed from the company, which owns the patent "Johnson & Johnson."

The undersigned and his legal representative searched for over five hours on the Internet trying to obtain the product protected by the patent. The Johnson & Johnson website, as well as all the companies affiliated with Johnson & Johnson, were searched without any success.

A search, based on the chemicals disclosed by the Sipos patent, was also performed without any success.

At this point, the undersigned believes that Sipos was not able to release a product to the market based on US Patent No. 4,091,090 because he encountered the same problems encountered by the undersigned and his staff.

The undersigned believes that the Sipos formulation was never released to the market because the formulation is non-operative.

The second step of the experiment was to conduct an evaporation test with the formulation of the Castillo reference and the formulation of the present invention.

Ten grams of each formulation were placed on glassine paper and then spread out so that each sample had the same surface area. The results are as follows:

Time (min)	Weight (gm)	
	Betacaine Plus Castillo reference	Betacaine Gel Present invention
5	9.999	9.289
10	9.999	8.718
15	9.998	8.037
20	9.998	7.348
30	9.996	7.035
45	9.996	5.52
60	9.996	4.943
90	9.996	4.3
1020	9.996	2.19

As can be seen from the results of the test, the formulation of the Castillo ref erence DOES NOT evaporate.

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The formulation of the present invention rapidly evaporates.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application of any patent issuing thereon.

Date:

10-7-2002



James Castillo